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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,108	04/06/2000	Kenneth Eliot Sherman		7634

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CAROLINE NASH  
NASH & TITUS, LLC  
21402 UNISON ROAD  
MIDDLEBURG, VA 20177

EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/27/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/544,108

Applicant(s)

SHERMAN, KENNETH ELIOT

Examiner

Tim Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

This Non-Final Office Action is responsive to the communications sent July 17, 2002 and September 3, 2003. Please note the Examiner of Record for this application has changed to Tim Brown. The Examiner makes the following observations in view of the prosecution history.

The rejection of claims 10 and 11 under § 112, second paragraph is *withdrawn* in view of Applicants' amendment. The provisional rejection of claims 7, 8, 10-17 and 19-24 under the doctrine of non-statutory double patenting is *maintained*.

### ***Terminal Disclaimer***

Applicants' terminal disclaimer submitted August 9, 2002 has been received. The terminal disclaimer is being processed. The outstanding non-statutory double patenting rejection will be withdrawn upon approval of the terminal disclaimer.

### ***Claim Objections***

Claim 23 is objected to because the language "Thymosin -1" presents a typographical error. The claim has been interpreted as being drawn to thymonsin alpha-1 for examination purposes.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite because it lacks antecedent basis for "said  $\alpha$ -interferon." Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 3, 4-8, 10-17 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoofnagle in view of Huang and Mutchnick.**

Applicants' invention is a method and composition for treating a human HCV infection wherein alpha interferon is administered with either thymosin, or a thymosin fragment. The invention provides that the alpha interferon may comprise alpha 2-B interferon, and that the thymosin or its fragment may comprise thymosin alpha-1, or thymosin fraction 5 (TF5). Applicants also claim specific dosages within the composition for alpha interferon, thymosin alpha-1 and TF5. Applicants' interferon may be produced recombinantly.

Hoofnagle teaches the main feature of Applicants' invention which is treating HCV infection with recombinant alpha 2-b interferon (see p. 260). Like Applicants' invention, one to three million alpha 2-b interferon units are given per administration (Id.). While Hoofnagle suggests combination therapy with other viral agents (see p. 261), Hoofnagle does not expressly teach the co-administration of alpha interferon with thymosin as claimed. However, Huang teaches treating HBV using interferon and thymosin in combination therapy. At the time of

Applicants' invention, it would have been obvious to modify Hoofnagle to include the co-administration of thymosin as taught by Huang. This is because Mutchnick would have taught the skilled artisan that thymosin generally enhances the immune system by accelerating lymphocyte maturation, increasing T cell function and reconstituting immune defects (see p. 409). Thus, the skilled artisan would have reasonably expected Hoofnagle's alpha-interferon HCV treatment to benefit from Huang's co-administration of thymosin since thymosin was shown to produce a general improvement in the immune system.

Note that Mutchnick overcomes the failure of Hoofnagle and Huang to teach TF5 or thymosin alpha-1. Mutchnick does this by teaching a method and composition for treating a hepatic viral infection using either TF5 or thymosin alpha-1. As noted above, Mutchnick teaches that TF5 and thymosin alpha-1 generally enhance the immune system. Therefore, one of ordinary skill would have been motivated to modify Hoofnagle and Huang to include the co-administration of either TF5 or thymosin alpha-1 in order to boost the immune system of the subject.

Also note the combination of references does not expressly teach administering either TF5, or thymosin alpha-1, at about 900-1200 mg/m<sup>2</sup> subject body surface. However, the Examiner asserts that deriving a therapeutic concentration for an antiviral agent is conventional in the art. Thus, modifying the asserted combination to include TF5, or thymosin alpha-1, at about 900-1200 mg/m<sup>2</sup> subject body surface would have been obvious to the skilled artisan at the time of Applicants' invention.

*Response to Arguments*

Rejection of Claims 7, 8, 12-14, 16, 17 and 21 under 102(b)

Applicants' amendment overcomes the rejection of claims 7, 8, 12-14, 16, 17 and 21 under 102(b). This results because Huang et al. do not teach a composition comprising alpha interferon. Accordingly, the rejection of claims 7, 8, 12-14, 16, 17 and 21 as anticipated by Huang et al. is withdrawn.

Rejection of Claims 10, 11, 15, 19, 20 and 22-24 Under 103(a)

Applicants argue the combination of Huang et al. ("Huang") and Hoofnagle et al. ("Hoofnagle") does not teach the particular dosage of their composition. The Examiner asserts deriving an effective dosage for a therapeutic composition is conventional to anti-viral therapy. That is, the teachings of the prior art would enable an artisan of ordinary skill to arrive at the claimed dosage based on conventional antiviral treatment schemes.

Applicants argue Hoofnagle does not teach or suggest the combination of alpha-interferon and thymosin, nor the effective amount of this combination. This argument is moot in view of the new art rejection appearing above. Applicants' arguments with respect to Goldstein et al. and Birr et al. are also moot in view of the new grounds of rejection.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown  
Examiner  
Art Unit 1648

tb

*Sharon Foley*  
*Patent Examiner, 1648*